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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,377

01/18/2006

Stuart Bevan

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

11/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,377	Applicant(s) BEVAN ET AL.	
	Examiner Jon M. Lockard	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to polynucleotides.

Group II, claim(s) 5-8 and 15-16, in so far as they are drawn to a method for identifying an agent that modulates a nociceptive response *in an organism*, wherein the agent is a *peptide*.

Group III, claim(s) 5-8 and 15-16, in so far as they are drawn to a method for identifying an agent that modulates a nociceptive response *in an organism*, wherein the agent is a *peptidomimetic*.

Group IV, claim(s) 5-8 and 15-16, in so far as they are drawn to a method for identifying an agent that modulates a nociceptive response *in an organism*, wherein the agent is a *chemical*.

Group V, claim(s) 5-8 and 15-16, in so far as they are drawn to a method for identifying an agent that modulates a nociceptive response *in an organism*, wherein the agent is a *nucleic acid*.

Group VI, claim(s) 5 and 9-10, in so far as they are drawn to a method for identifying an agent that modulates a nociceptive response *in a cell*.

Group VII, claim(s) 11-14 and 18-19, in so far as they are drawn to a method for modulating nociceptive pain in an organism comprising administering an agent that *modulates the activity of a polypeptide*, wherein the agent is a *peptide*.

Group VIII, claim(s) 11-14 and 18-19, in so far as they are drawn to a method for modulating nociceptive pain in an organism comprising administering an agent that *modulates the activity of a polypeptide*, wherein the agent is a *peptidomimetic*.

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Group IX, claim(s) 11-14 and 18-19, in so far as they are drawn to a method for modulating nociceptive pain in an organism comprising administering an agent that *modulates the activity of a polypeptide*, wherein the agent is a *chemical*.

Group X, claim(s) 11-14 and 18-19, in so far as they are drawn to a method for modulating nociceptive pain in an organism comprising administering an agent that *modulates the activity of a polypeptide*, wherein the agent is a *nucleic acid*.

Group XI, claim(s) 17 and 20, drawn to a method for reducing nociceptive pain in an organism comprising administering an agent that *modulates the function of a polynucleotide*.

Group XII, claim(s) 21, drawn to polypeptides.

Group XIII, claim(s) 22, drawn to a molecule of undisclosed constitution which binds a polypeptide.

Group XIV, claim(s) 23, drawn to antibodies.

2. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. § 1.475(B-D), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, an isolated nucleic acid sequence encoding an ANKTM1-related polypeptide. Because the technical features of the Groups II-XIV inventions is not present in the Group I claims, unity of invention is lacking. Moreover, The polynucleotides of Group I, the polypeptides of Group XII, the molecules of undisclosed constitution of Group XIII, and the antibodies of Group XIV are structurally and functionally different chemical compounds, each of which can be made and used without the other compound. The methods of Groups II-XII require compounds, which are functionally different from each other, and each can be made and used without the other. Lack of unity is shown because these compounds and methods lack a common utility which is based upon a common technical feature which has been identified as the basis for that common utility.

Further Restriction Within Groups I-XIV

3. Whichever Group is elected, further restriction within the elected Group is required to one of the following:

One (1) polypeptide according to SEQ ID NO: 1, 2, and 4.

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4. The individual polypeptides and antibodies which bind said polypeptide do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each polypeptide and antibody represents a structurally and functionally different chemical compound from each other, which can be made and used without the other compounds, and therefore the methods of using the compounds are also different methods. Lack of unity is shown because these compounds and methods lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

5. **Applicants are advised that this is not a species election.**

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

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Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 7:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

/J. M. L./
November 8, 2007

/Jon M Lockard/
Examiner, Art Unit 1647